



REC'D PCT/PTO 03/08/97
20-203
10/523256
INVESTOR IN PEOPLE

REC'D 01 SEP 2003	
WIPO	PCT

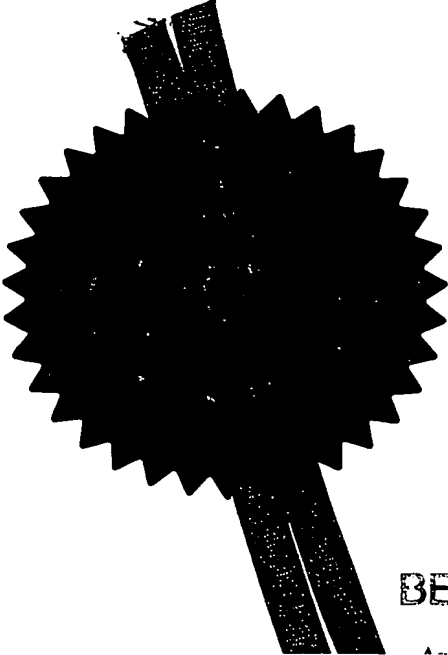
The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



P. Mahoney

Signed

Dated 21 July 2003

BEST AVAILABLE COPY

**PRIORITY
DOCUMENT**
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

The
Patent
Office

- 1 AUG 2002

NEWPORT

1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
NP23 5BA
01 AUG 02 E737686-2 D10009
P01/7780 0.00 0217802.8

1. Your Reference **CGP/PG4902**
2. Patent application number **0217802.8**
(The Patent office will fill in this part)
3. Full name, address and postcode of the or of each applicant (underline all surnames)
**GLAXO GROUP LIMITED
GLAXO WELLCOME HOUSE
BERKELEY AVENUE
GREENFORD
MIDDLESEX
UB6 0NN
UNITED KINGDOM**
Patents ADP number (if you know it) **473587003**
If the applicant is a corporate body, give the country/state of its corporation
4. Title of the invention **A FLUID DISPENSING DEVICE**
5. Name of your agent (if you have one) **DR CHRISTOPHER GERARD PIKE
PIKE & CO.
HAYES LOFT
68A HAYES PLACE
MARLOW
BUCKS
SL7 2BT**
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)
Patents ADP number (if you know it) **7497928002**
6. If you are declaring priority from one or more earlier patent applications, give the country and date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country	Priority application number (if you know it)	Date of Filing (day / month / year)
---------	--	-------------------------------------
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing (day / month / year)
-------------------------------	-------------------------------------
8. Is a statement of inventorship and of right to grant a patent required in support of this request? (Answer yes if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d)) **YES**
9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form 0

Description 18

Claim(s) 6

Abstract 1

Drawing(s) 4

10. If you are also filing any of the following,
state how many against each item.

Priority Documents

Translations of priority documents

Statement of inventorship and right
to grant of a patent (*Patents Form 7/77*)


Request for preliminary examination
and search (*Patent Form 9/77*)

Request for substantive examination
(*Patent Form 10/77*)

Any other documents
(*please specify*)

11.

I/We request the grant of a patent on the basis of this application


Signature Christopher Gerard Pike
AGENT FOR THE APPLICANTS

31 July 2002

12. Name and daytime telephone number of
person to contact in the United Kingdom

Dr. Christopher G. Pike
01628 471869

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patent Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

Additional Agents

BLAKEY, Alison Jane
CRAWLEY, Karen
CONNELL, Anthony Christopher
DALTON, Marcus Jonathan William
DAWSON, Hugh B
DOLTON, Peter I
EASEMAN, Richard Lewis
FILLER, Wendy Anne
GIDDINGS, Peter John
HACKETT, Ruth Elizabeth
HOCKLEY, Sin Catherine
LAWTON, Peter Philip
LEAROYD, Stephanie Anne
LUBIENSKI, Michael John
PRIVETT, Kathryn Louise
QUILLIN, Helen Kaye

REED, Michael A
REES, Marion L
REEVES, Julie Frances
ROBERTS, David
RUSSELL, Brian John
RUTTER, Keith
STEPHEN, Robert
STOTT, Michael John
TEUTEN, Andrew J
THOMPSON, Clive Beresford
THORNLEY, Rachel M
TYRRELL, Arthur William Russell
VALENTINE, Jill Barbara
WALKER, Ralph Francis
WATERS, David Martin
WEST, Vivien
WHITE, Susan Mary

ADDRESS

Glaxo Wellcome plc
Glaxo Wellcome House
Berkeley Avenue
Greenford
Middlesex
UB6 0NN
Great Britain

A fluid dispensing device

The present invention relates to a medicament dispenser and in particular to fluid dispensing device for use as a nasal inhaler.

- 5 It is well known to provide a medicament dispenser in which fluid is dispensed via a nozzle or orifice upon the application of a force by a user to a single actuation lever or button. Such devices may be arranged to dispense a single dose or may alternatively be arranged with a reservoir containing several doses to be dispensed.

- 10 It is a problem with such a prior art spray that because only one finger actuated member is used to causing spraying the spray can be difficult to operate because a reaction force has to be applied to the device to counteract the force applied to the finger actuated member.

It is an object of this invention to provide a fluid dispensing device that is easier to use and in particular a device which provides a more efficient dispensing of fluid.

- 15 According to a first aspect of the invention there is provided a fluid dispensing device for spraying a fluid into a body cavity comprising a housing, a nozzle for insertion into a body cavity, a fluid discharge device moveably housed within the housing, the fluid discharge device comprising a container for storing the fluid to be dispensed and a compression pump having a suction inlet located within the container and a
20 discharge outlet at one end of the container for transferring fluid from the pump to the nozzle and a finger operable means to apply a force to the container to move the container towards the nozzle so as to actuate the pump wherein the finger operable means comprises of at least one lever pivotally supported within the housing and driveably connected to the container so as to urge the container towards the nozzle
25 when the or each lever is rotated by a user.

Preferably, there may be two opposing levers each of which may be pivotally connected to part of the housing and may be driveably connected to the container so

as to urge the container towards the nozzle when the levers are squeezed together by a user.

The or each lever may be driveably connected to the container near to said one end of the container.

- 5 The or each lever may have a toothed portion for engagement with a toothed rack attached to the container so as to form the driveable connection therebetween.

The container may have a longitudinal axis and the or each toothed rack may extend parallel to the longitudinal axis of the container.

- Each toothed rack may have two sets of opposed teeth, a first set of teeth for
10 engagement with a first lever and a second set of teeth for engagement with a second lever.

The container may have a neck portion at said one end and the or each toothed rack may be attached to the neck portion of the container so as to form in combination with each lever the driveable connection.

- 15 Preferably, the container may have two toothed racks attached thereto.

The two toothed racks may be arranged on opposite sides of the neck portion.

The neck portion may have a cylindrical outer surface and the two toothed racks may be arranged diametrically opposite with respect to the neck portion.

- Advantageously, the or each toothed rack may be connected to a collar used to
20 attach the or each toothed rack to the neck portion of the container.

Preferably, the or each toothed rack may be formed as an integral part of the collar.

The collar may have two toothed racks formed as an integral part thereof.

The cylindrical outer surface of the neck portion may have a circumferentially extending groove formed therein in which a portion of the collar is engaged.

The circumferentially extending groove may define an annular abutment surface against which the portion of the collar reacts when the or each lever is rotated to urge the container towards the nozzle.

The or each lever may have first and second toothed portions for engagement with
5 respective racks attached to the container.

There may be a first lever located on one side of the container and a second lever located on an opposite side of the container each having first and second toothed portions for engagement with respective racks attached to the container, therebeing a first rack having a first set of teeth for engagement with the first toothed portion of
10 the first lever and a second set of teeth for engagement with the first toothed portion of the second lever and a second rack having a first set of teeth for engagement with the second toothed portion of the first lever and a second set of teeth for engagement with the second toothed portion of the second lever.

The or each lever may be U-shaped in cross-section having first and second flanges
15 joined together by a bridging portion.

In which case, the first flange may have an end portion forming said first toothed portion and the second flange may have an end portion forming said second toothed portion.

The or each lever may be pivotally supported within the housing by a pivotal
20 connection between the lever and part of the housing.

The housing may have a front wall, a rear wall and two opposing side walls and the or each lever may be pivotally connected to the front and rear walls.

The housing may have a front wall, a rear wall and two opposing side walls and at least one of the front wall and the rear wall may have an aperture therein to view the
25 level of the fluid in the container.

Each lever may project outwardly from the housing through an aperture formed in a respective one of the side walls.

The part of each lever which projects from the aperture may form a finger grip.

Alternatively, the nozzle may be formed as part of a body member and the or each
5 lever may be pivotally supported within the housing by a pivotal connection between the lever the body member.

According to a second aspect of the invention there is provided a fluid discharge device for use in a fluid dispensing device in accordance with the first aspect of the invention the fluid discharging device comprising a container having a longitudinal
10 axis for storing a fluid to be dispensed and a compression pump attached to one end of the container, the pump having a suction inlet located within the container and a discharge outlet for transferring, in use, fluid from the pump to a nozzle wherein the container has at least one toothed rack attached thereto.

The or each toothed rack may extend parallel to the longitudinal axis of the
15 container.

The or each toothed rack may be attached to the container by being formed as an integral part of a collar attached to a neck portion of the container.

Alternatively, the or each rack may be attached to the container by being formed as an integral part of the container.

20 According to a third aspect of the invention there is provided a housing assembly for a fluid discharge device, the housing assembly comprising a housing for moveably supporting the fluid discharge device, a body having a nozzle extending therefrom for insertion into a body cavity and at least one toothed lever pivotally supported within the housing for toothed engagement with a container forming part of the fluid
25 discharge device.

The fluid discharge device is one aspect in accordance with the first aspect of the invention (i.e. a pump-type device). In another aspect, the fluid discharge device is an aerosol container having a dispensing valve (typically, a metering valve, such as a slide valve type metering valve) of the type well-known for use in metered dose inhaler (MDI) type medicament dispensers.

By metered dose inhaler (MDI) it is meant a discharge device suitable for dispensing medicament in aerosol form, wherein the medicament is comprised in an aerosol container suitable for containing a propellant-based aerosol medicament formulation. The aerosol container is typically provided with a metering valve, for example a slide valve, for release of the aerosol form medicament formulation to the patient. The aerosol container is generally designed to deliver a predetermined dose of medicament upon each actuation by means of the valve, which can be opened either by depressing the valve while the container is held stationary or by depressing the container while the valve is held stationary.

Where the medicament container is an aerosol container, the valve typically comprises a valve body having an inlet port through which a medicament aerosol formulation may enter said valve body, an outlet port through which the aerosol may exit the valve body and an open/close mechanism by means of which flow through said outlet port is controllable.

The valve may be a slide valve wherein the open/close mechanism comprises a sealing ring and receivable by the sealing ring a valve stem having a dispensing passage, the valve stem being slidably movable within the ring from a valve-closed to a valve-open position in which the interior of the valve body is in communication with the exterior of the valve body via the dispensing passage.

Typically, the valve is a metering valve. The metering volumes are typically from 10 to 100 μl , such as 25 μl , 50 μl or 63 μl . Suitably, the valve body defines a metering chamber for metering an amount of medicament formulation and an open/close

mechanism by means of which the flow through the inlet port to the metering chamber is controllable. Preferably, the valve body has a sampling chamber in communication with the metering chamber via a second inlet port, said inlet port being controllable by means of an open/close mechanism thereby regulating the flow
5 of medicament formulation into the metering chamber.

The valve may also comprise a 'free flow aerosol valve' having a chamber and a valve stem extending into the chamber and movable relative to the chamber between dispensing and non-dispensing positions. The valve stem has a
10 configuration and the chamber has an internal configuration such that a metered volume is defined therebetween and such that during movement between is non-dispensing and dispensing positions the valve stem sequentially: (i) allows free flow of aerosol formulation into the chamber, (ii) defines a closed metered volume for
15 pressurized aerosol formulation between the external surface of the valve stem and internal surface of the chamber, and (iii) moves with the closed metered volume within the chamber without decreasing the volume of the closed metered volume until the metered volume communicates with an outlet passage thereby allowing dispensing of the metered volume of pressurized aerosol formulation.

20 There may be a first lever located on one side of the container and a second lever located on an opposite side of the container.

The or each lever may have first and second toothed portions for engagement with respective racks attached to the container.

The or each lever may be U-shaped in cross-section having first and second flanges
25 joined together by a bridging portion.

The first flange may have an end portion forming said first toothed portion and the second flange may have an end portion forming said second toothed portion.

The housing may have a front wall, a rear wall and two opposing side walls and at least one of the front wall and the rear wall may have an aperture therein to view the level of the fluid in the container.

The or each lever may be pivotally supported within the housing by a pivotal
5 connection between the lever and part of the housing.

The housing may have a front wall, a rear wall and two opposing side walls and the or each lever may be pivotally connected to the front and rear walls.

Each lever may project outwardly from the housing through a respective aperture formed in a one of the side walls.

10 The part of each lever which projects from the aperture may form a finger grip.

Alternatively, the or each lever may be pivotally supported within the housing by a pivotal connection between the body and the respective lever.

The invention will now be described further with reference to the accompanying drawing in which:-

15 Fig. 1 is a front view a fluid dispensing device according to the invention in a ready for use state;

Fig. 2 is a pictorial view of a fluid discharge device forming part of the fluid dispensing device shown in Fig. 1;

Fig. 3 is a side view of the fluid dispensing device shown in Fig.1;

20 Fig.4 is staggered cross-section through the fluid dispensing device shown in Fig. 1 showing the fluid discharge device in a ready to use state;

Fig.5 is a staggered cross-section through the fluid dispensing device shown in Fig.1 showing the fluid discharge device in a discharged state;

Fig.6 is an enlarged cross-section along the line X-X on Fig.4; and

Fig.7 is an enlarged side view of a neck portion of fluid reservoir forming part of the fluid discharge device.

With reference to figures 1 to 7 there is shown a fluid dispensing device 5 for spraying a fluid into a body cavity comprising a housing 9, a nozzle 11 for insertion into a body cavity and a fluid discharge device 8 moveably housed within the housing 9. The fluid discharge device 8 comprises of a container 30 for storing the fluid to be dispensed and a compression pump 29 having a suction inlet 32 located within the container 30 and a discharge outlet 31 at one end of the container 30 for transferring fluid from the pump to the nozzle 11. A finger operable means 20, 21 is provided to apply a force to the container 30 to move the container 30 towards the nozzle 11 so as to actuate the pump.

The finger operable means is in the form of at least one but preferably two opposing levers 20, 21 each of which is pivotally supported within the housing 9 and is driveably connected to the container 30 so as to urge the container 30 towards the nozzle 11 when each lever 20, 21 is rotated by a user. When there are two levers forming first and second levers 20, 21, then the levers 20, 21 are rotated by being squeezed together by a user.

In more detail, the fluid dispensing device 5 comprises of a housing assembly and the fluid discharge device 8. The housing assembly comprises of the housing 9 for moveably supporting the fluid discharge device 8, a body 6 having the nozzle 11 extending therefrom, a protective end cap 7 for engagement with the body 6 to protect the dispensing nozzle 11 and the two levers 20, 21 pivotally supported within the housing 9.

It is envisaged that the end cap 7 may be attached to the body by a flexible strap or tether which could be moulded as part of the end cap 7 or the end cap 7 and the body could be made as a single component.

The body 6 and the nozzle 11 are made as a single part from a plastic material such as polypropylene and the body 6 is adapted at a lower end for engagement with an

upper end of the housing 9. The body 6 and the housing 9 are fixed together by any suitable means.

The housing 9 defines a cavity 10 formed by a front wall 12, a rear wall 13 and first and second end walls 14a, 14b. An aperture 28 is formed in the front wall 12 of the
5 housing 9 so as to allow a user to view the contents of the container. If required an aperture could also be formed in the rear wall 13.

The housing 9 is formed by two separate shells which are joined together to form the housing 9. One of the shells forms the front wall 12 and part of the two side walls 14a, 14b and the other shell forms the rear wall 13 and the remaining part of the two
10 side walls 14a, 14b.

The discharge outlet from the pump is in the form of a tubular delivery tube 31 and a tubular guide in the form of an outlet tube 16 is formed within the nozzle 11 to align and locate the delivery tube 31 correctly with respect to the nozzle 11.

An annular abutment 17 is formed at the end of the outlet tube 16. The annular
15 abutment 17 defines the entry to an orifice 15 through which fluid can flow in use and is arranged for abutment with an end of the delivery tube 31.

The fluid discharge device 8 has a longitudinal axis L-L co-incident with a longitudinal axis of the container 30 and a longitudinal axis of the tubular delivery tube 31. The nozzle 11 has a longitudinal axis Y-Y which is aligned with the
20 longitudinal axis L-L of the fluid discharge device 8 so that when the pump is actuated the force applied to the tubular delivery tube 31 is along the longitudinal axis of the tubular delivery tube 31 and no bending or deflection of the delivery tube 31 will occur due to the applied force.

Each of the first and second levers 20, 21 is driveably connected to the container 30
25 near to said one end of the container 30 where the container terminates in a neck 29.

To form the driveable connection each of the first and second lever 20,21 has a toothed portion 22a, 23a; 22b, 23b for engagement with a respective toothed rack 32, 33 attached to the container 30 and in particular to the neck portion 29 of the container 30. Each of the racks 32, 33 is arranged so as to extend parallel to the longitudinal axis of the container 30.

Each of toothed racks 32, 33 has two sets of opposed teeth, a first set of teeth 32a, 33a for engagement with the first lever 20 and a second set of teeth 32b, 33b for engagement with the second lever 21.

The neck portion 29 of the container 30 has a cylindrical outer surface 38 and the two toothed racks 32, 33 are arranged on opposite sides of the neck portion 29 so that the two toothed racks 32, 33 are arranged diametrically opposite with respect to the neck portion 29.

Each of the toothed racks 32, 33 is connected to a collar 40 used to attach the toothed racks 32, 33 to the neck portion 29 of the container 30.

The toothed racks 32, 33 are formed as an integral part of the collar 40 so that the collar 40 has the two toothed racks 32, 33 formed as an integral part of it.

The cylindrical outer surface 38 of the neck portion 29 has a circumferentially extending groove 39 formed therein in which a portion of the collar 40 in the form of a flange 41 is engaged. The flange 41 has a slot 42 formed in one edge and a depression 43 formed in an opposite edge. The slot 42 allows the flange to be expanded over the neck 29 so as to allow it to be engaged with the groove 39 and the depression 43 reduces the thickness of the flange 41 to assist in this procedure.

It will however be appreciated that other methods could be used to secure the collar 40 to the neck 29 of the container 30. However, this method is advantageous in that it allow the collar 40 to be snapped onto a standard fluid discharge device 8 without the need for special tools or equipment.

The circumferentially extending groove 39 defines an annular abutment surface 44 against which the flange portion 41 of the collar 40 can react when the two levers 20, 21 are rotated to urge the container 30 towards the nozzle 11.

The first lever 20 is located on one side of the container 30 and the second lever is
5 located on an opposite side of the container 30. Each of the first and second levers 20, 21 has first and second toothed portions 22a, 23a; 22b, 23b for engagement with the two racks 32, 33 attached to the container 30.

A first rack 32 of the two racks has a first set of teeth 32a for engagement with the first toothed portion 22a of the first lever 20 and a second set of teeth 32b for
10 engagement with the first toothed portion 22b of the second lever 21 and a second rack 33 of the two racks has a first set of teeth 33a for engagement with the second toothed portion 23a of the first lever 20 and a second set of teeth 33b for engagement with the second toothed portion 23b of the second lever 20.

Each of the two levers 20, 21 is U-shaped in cross-section and has first and second
15 flanges 24a, 24b; 25a, 25b joined together by a bridging portion 26, 27.

The first flange 24a of the first lever 20 has an end portion forming said first toothed portion 22a and the second flange 24b of the first lever 20 has an end portion forming said second toothed portion 23a. Similarly, the first flange 25a of the second lever 21 has an end portion forming said first toothed portion 22b and the second
20 flange 25b of the second lever 21 has an end portion forming said second toothed portion 23b.

Each of the levers 20, 21 is pivotally supported within the housing 9 by a pivotal connection between the respective lever 20, 21 and part of the housing 9 in the form of the front and rear walls 12 and 13.

25 The front wall 12 has two cylindrical pivot pins 18a, 18b formed as an integral part thereof and the rear wall 13 has two cylindrical pins 19a, 19b formed as an integral part thereof.

The first lever 20 has an aperture 45a formed in the first flange 24a for co-operation with the pivot pin 18a and an aperture 45b formed in the second flange 24b for co-operation with the pivot pin 19a. Similarly, the second lever 21 has an aperture 46a formed in the first flange 25a for co-operation with the pivot pin 18b and an aperture
5 46b formed in the second flange 25b for co-operation with the pivot pin 19b.

The pivot pins 18a, 19a; 18b, 19b form in combination with the apertures 45a, 45b; 46a, 46b pivotal connections at an upper end of the levers 20, 21 between the levers 20, 21 and the housing 9.

Each of the levers 20, 21 projects outwardly from the housing 9 through an aperture
10 47a, 47b formed in a respective one of the side walls 14a, 14b.

As previously discussed the housing 9 is formed by two separate shells which are joined together to form the housing 9. Each of the apertures 47a, 47b is therefore formed by complementary cut-outs in the side walls 14a, 14b of the two shells that form the housing 9.

15 To assist a user in using the fluid dispensing device a part of each lever 20, 21 which projects from the aperture 47a, 47b forms a finger grip.

It will be appreciated that the levers 20, 21 could be pivotally attached to the housing in some other manner for example separate pivot pins could be used or the levers could have pivot pins formed as an integral part for co-operation with apertures
20 formed in the housing 9. It will also be appreciated that the levers could be pivotally connected to another part of the housing such as the side walls.

It will further be appreciated that the housing could be made as one-part and that the body and the housing could be made as one part.

In addition each lever 20, 21 could be pivotally supported within the housing 9 by a
25 pivotal connection between each lever 20, 21 and the body member 6.

The fluid discharge device 8 is in most respects conventional and will only be described briefly herein.

The fluid discharge device 8 has a longitudinal axis L-L corresponding to the longitudinal axis of the container 30. The container 30 defines a reservoir containing
5 several doses of the fluid to be dispensed and a compression pump is attached to the neck 29 formed at one end of the container 30. The pump is used to pump the fluid out of the container 30.

The pump has a suction inlet located within the container 30 and a discharge outlet for transferring, in use, fluid from the pump to the nozzle 11.

10 The neck 29 of the container 30 has the two toothed racks 32, 33 attached thereto. Each of the toothed racks 32, 33 extends parallel to the longitudinal axis L-L of the container.

Preferably, each of the toothed racks 32, 33 is attached to the container by being formed as an integral part of the collar 40 attached to the neck portion 29 of the
15 container 30.

Alternatively, each of the toothed racks can be attached to the container by being formed as an integral part of the container. That is to say if the container is moulded from plastic the two toothed racks 32, 33 are moulded as part of the container 30.

The container 30 as shown is made from a translucent or transparent plastics
20 material however it will be appreciate that it could be made from other translucent or transparent materials such as glass in which case a collar would need to be used.

The pump includes a plunger (not shown) slidably engaged within a pump casing which defines a chamber (not shown) sized to accommodate a single dose of fluid. The plunger is attached to the tubular delivery tube 31 which is arranged to extend
25 from one end of the pump for co-operation with the outlet tube 16 of the dispensing nozzle 11. The plunger includes a piston (not shown) slidably supported in the chamber formed in the pump casing.

The fluid is discharged through a discharge channel defined by the tubular delivery tube 31 into the orifice 15 of the dispensing nozzle 11.

The size of chamber is such that it accommodates a single dose of fluid, the diameter of the chamber and piston combined with the stroke of the plunger being
5 such that a full stroke of the plunger in the chamber will produce a change in volume equal to a single dose of fluid.

The pump casing is connected to the container 30 such that when the piston is moved by a return spring (not shown) into a start position a new dose of fluid is drawn into the cylinder via the suction inlet in the form of a pick-up tube from the
10 container 30 ready for discharge.

Assembly and operation of the fluid dispensing device is as follows.

Fig.4 shows the fluid dispensing device 5 in a ready to use state in which the two levers 20, 21 are in a ready for use position.

A fluid discharge device 8 has already been inserted into the housing 9 by lifting the
15 two levers 20, 21 fully upward and inserting the container 30 into the housing until the delivery tube 31 fully engages with the outlet tube 16. The two levers 20, 21 have then been folded down into the position shown in Fig. 4 such that the toothed portions 22a, 23a, 22b, 23b are engaged with the racks 32, 33. The levers 20, 21 in this position are used to hold the fluid discharge device 8 within the housing 9 but if
20 required the container 30 could be slidably engageable with one or more support structures (not shown) to assist with the location and retention of the fluid discharge device 8 in the housing 9.

The next step is for a user to grasp the fluid dispensing device 5 by the two levers 20, 21. Provided that only a light pressure is applied to the levers 20, 21 no fluid will
25 be discharged due to static friction in the mechanism and the user is able to manoeuvre the dispensing nozzle 11 of the fluid dispensing device 5 into the body orifice into which fluid is required to be dispensed. If the user then squeezes the two

- 15 -

levers 20, 21 together with increasing force the static friction between the toothed portions 22a, 23a, 22b, 23b and the racks 32, 33 and the levers 20, 21 and the pivot pins 18a, 19a; 18b, 19b will eventually be overcome and the interaction of the toothed portions 22a, 23a, 22b, 23b with the racks 32, 33 will then cause the
5 container 30 to be moved rapidly towards the nozzle 11.

However, because the end of the delivery tube 31 is in abutting contact with the annular abutment 17, the delivery tube 31 cannot move in the same direction.

The effect of this is to cause the delivery tube 31 to push the plunger into the pump casing thereby moving the piston of the pump in the cylinder. This movement
10 causes fluid to be expelled from the cylinder into the delivery tube 31. The fluid forced into the delivery tube is then transferred into the orifice 15 from where it is expelled as a fine spray into the body orifice.

At the end of the delivery stage when the fluid discharge device has been discharged the two levers 20, 21 have been rotated so that they lie close to or flush with the side
15 walls 14a, 14b as shown in Fig.5.

Upon releasing the pressure applied to the levers 20, 21 the delivery tube 31 is urged out of the pump casing by the internal return spring and causes fluid to be drawn up the pick-up tube 32 to re-fill the cylinder. If necessary an external spring can be provided between the nozzle 11 and the collar 40 to assist with the return
20 action.

The actuating procedure can then be repeated until all of the fluid in the container has been used. However, only one or two doses of fluid are normally administered at a time.

When the container is empty a new fluid discharge device 8 is loaded into the
25 housing 9 thereby restoring the fluid dispensing device 5 into a useable condition.

It is envisaged that the fluid dispensing device could be sold as two separate items. A fluid discharge device could be sold for fitment into a housing assembly and a housing assembly could be sold into which a fluid discharge device could be fitted.

Although the invention has been described in relation to an arrangement where the
5 driving connection between the levers and the container is made via a toothed drive it will be appreciated that alternative means for providing a driving connection could be used. For example, the levers could frictionally engage with the container or another component connected to the container to move the container.

It may be appreciated that any of the parts of the dispenser device which contact the
10 fluid may be coated with materials such as fluoropolymer materials (e.g. PTFE or FEP) which reduce the tendency of medicament to adhere thereto. Any movable parts may also have coatings applied thereto which enhance their desired movement characteristics. Frictional coatings may therefore be applied to enhance frictional contact and lubricants (e.g. silicone oil) used to reduce frictional contact as
15 necessary.

The dispenser device of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders such as asthma and chronic obstructive pulmonary disease (COPD), bronchitis and chest infections. Appropriate
20 medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g. as the sodium salt), ketotifen or nedocromil (e.g. as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g.,
25 methapyrilene; anti-inflammatories, e.g., beclomethasone (e.g. as the dipropionate ester), fluticasone (e.g. as the propionate ester), flunisolide, budesonide, rofleponide, mometasone e.g. as the furoate ester), ciclesonide, triamcinolone (e.g. as the acetate) or 6 α , 9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxy-androsta-1,4-diene-17 β -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester;

antitussives, e.g., noscapine; bronchodilators, e.g., albuterol (e.g. as free base or sulphate), salmeterol (e.g. as xinafoate), ephedrine, adrenaline, fenoterol (e.g. as hydrobromide), formoterol (e.g. as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g. as acetate), reproterol (e.g. as
 5 hydrochloride), rimiterol, terbutaline (e.g. as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, e.g. 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate); α_4 integrin inhibitors e.g. (2S)-3-[4-({[4-
 10 (aminocarbonyl)-1-piperidiny]carbonyl}oxy)phenyl]-2-(((2S)-4-methyl-2-[[2-(2-methylphenoxy) acetyl]amino}pentanoyl)amino] propanoic acid (e.g. as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g. as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline
 15 theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise
 20 the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

25

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (eg as the fumarate salt) in combination with an anti-inflammatory steroid such as a
 30 beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of

fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

- 5 The medicaments are suitably employed in fluid form, generally as an aqueous solution. The solution may contain other components selected from inert solvents, excipients, preservative agents and any mixtures thereof.

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

- 10 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following
- 15 claims.
-

Claims

1. A fluid dispensing device for spraying a fluid into a body cavity comprising a housing, a nozzle for insertion into a body cavity, a fluid discharge device moveably housed within the housing, the fluid discharge device comprising a
5 container for storing the fluid to be dispensed and a compression pump having a suction inlet located within the container and a discharge outlet at one end of the container for transferring fluid from the pump to the nozzle and a finger operable means to apply a force to the container to move the
10 container towards the nozzle so as to actuate the pump wherein the finger operable means comprises of at least one lever pivotally supported within the housing and driveably connected to the container so as to urge the container towards the nozzle when the or each lever is rotated by a user.
2. A fluid dispensing device as claimed in claim 1 in which there are two
15 opposing levers each of which is pivotally connected to part of the housing and is driveably connected to the container so as to urge the container towards the nozzle when the levers are squeezed together by a user.
3. A fluid dispensing device as claimed in claim 1 or in claim 2 in which the or
each lever is driveably connected to the container near to said one end of the container.
- 20 4. A fluid dispensing device as claimed in of claims 1 to 3 in which the or each lever has a toothed portion for engagement with a toothed rack attached to the container so as to form the driveable connection therebetween.
5. A fluid dispensing device as claimed in claim 4 in which the container has a
25 longitudinal axis and the or each toothed rack extends parallel to the longitudinal axis of the container.
6. A fluid dispensing device as claimed in claim 4 or in claim 5 in which each toothed rack has two sets of opposed teeth, a first set of teeth for engagement

with a first lever and a second set of teeth for engagement with a second lever.

7. A fluid dispensing device as claimed in any of claims 4 to 6 in which the container has a neck portion at said one end and the or each toothed rack is attached to the neck portion of the container so as to form in combination with each lever the driveable connection.
8. A fluid dispensing device as claimed in any of claims 4 to 7 in which the container has two toothed racks attached thereto.
9. A fluid dispensing device as claimed in claim 8 when dependant upon claim 7 in which the two toothed racks are arranged on opposite sides of the neck portion.
10. A fluid dispensing device as claimed in claim 9 in which the neck portion has a cylindrical outer surface and the two toothed racks are arranged diametrically opposite with respect to the neck portion.
11. A fluid dispensing device as claimed in any of claims 7 to 10 in which the or each toothed rack is connected to a collar used to attach the or each toothed rack to the neck portion of the container.
12. A fluid dispensing device as claimed in claim 11 in which the or each toothed rack formed as an integral part of the collar.
13. A fluid dispensing device as claimed in claim 12 in which the collar has two toothed racks formed as an integral part thereof.
14. A fluid dispensing device as claimed in any of claims 11 to 13 in which the cylindrical outer surface of the neck portion has a circumferentially extending groove formed therein in which a portion of the collar is engaged.
15. A fluid dispensing device as claimed in claim 14 in which the circumferentially extending groove defines an annular abutment surface against which the

- 21 -

portion of the collar reacts when the or each lever is rotated to urge the container towards the nozzle.

16. A fluid dispensing device as claimed in any of claims 4 to 15 in which the or
each lever has first and second toothed portions for engagement with
5 respective racks attached to the container.
17. A fluid dispensing device as claimed in claim 16 in which there is a first lever
located on one side of the container and a second lever located on an
opposite side of the container each having first and second toothed portions
for engagement with respective racks attached to the container, therebeing a
10 first rack having a first set of teeth for engagement with the first toothed
portion of the first lever and a second set of teeth for engagement with the first
toothed portion of the second lever and a second rack having a first set of
teeth for engagement with the second toothed portion of the first lever and a
second set of teeth for engagement with the second toothed portion of the
15 second lever.
18. A fluid dispensing device as claimed in claim 16 or in claim 17 in which the or
each lever is U-shaped in cross-section having first and second flanges joined
together by a bridging portion.
19. A fluid dispensing device as claimed in claim 18 in which the first flange has
20 an end portion forming said first toothed portion and the second flange has an
end portion forming said second toothed portion.
20. A fluid dispensing device as claimed in any preceding claim in which the or
each lever is pivotally supported within the housing by a pivotal connection
between the lever and a part of the housing.
- 25 21. A fluid dispensing device as claimed in claim 20 in which the housing has a
front wall, a rear wall and two opposing side walls and the or each lever is
pivotally connected to the front and rear walls.

22. A fluid dispensing device as claimed in claim 20 or in claim 21 in which the housing has a front wall, a rear wall and two opposing side walls and at least one of the front wall and the rear wall has an aperture therein to view the level of the fluid in the container.
- 5 23. A fluid dispensing device as claimed in 21 or in claim 22 in which each lever projects outwardly from the housing through an aperture formed in a respective one of the side walls.
24. A fluid dispensing device as claimed in claim 23 in which the part of each lever which projects from the aperture forms a finger grip.
- 10 25. A fluid dispensing device as claimed in any of claims 1 to 19 in which the nozzle is formed as a part of a body member and the or each lever is pivotally supported within the housing by a pivotal connection between the lever and the body member.
- 15 26. A fluid discharge device for use in a fluid dispensing device as claimed in any of claims 1 to 25 wherein the fluid discharging device comprises of a container having a longitudinal axis for storing a fluid to be dispensed and a compression pump attached to one end of the container, the pump having a suction inlet located within the container and a discharge outlet for transferring, in use, fluid from the pump to a nozzle wherein the container has at least one toothed rack attached thereto.
- 20 27. A fluid discharge device as claimed in claim 26 in which the or each toothed rack extends parallel to the longitudinal axis of the container.
28. A fluid discharge device as claimed in claim 26 or in claim 27 in which the or each toothed rack is attached to the container by being formed as an integral part of a collar attached to a neck portion of the container.
- 25

29. A fluid discharge device as claimed in claim 26 or in claim 27 in which the or each rack is attached to the container by being formed as an integral part of the container.
- 5 30. A housing assembly for a fluid discharge device, the housing assembly comprising a housing for moveably supporting the fluid discharge device, a body having a nozzle extending therefrom for insertion into a body cavity and at least one toothed lever pivotally supported within the housing for toothed engagement with a container forming part of the fluid discharge device.
- 10 31. An assembly as claimed in claim 30 in which there is a first lever located on one side of the container and a second lever located on an opposite side of the container.
32. An assembly as claimed in claim 30 or in claim 31 in which the or each lever has first and second toothed portions for engagement with respective racks attached to the container.
- 15 33. An assembly as claimed in claim 32 in which the or each lever is U-shaped in cross-section having first and second flanges joined together by a bridging portion.
- 20 34. An assembly as claimed in claim 33 in which the first flange has an end portion forming said first toothed portion and the second flange has an end portion forming said second toothed portion.
35. An assembly as claimed in any of claims 30 to 34 in which the housing has a front wall, a rear wall and two opposing side walls and at least one of the front wall and the rear wall has an aperture therein to view the level of the fluid in the container.
- 25 36. An assembly as claimed in any of claims 30 to 35 in which the or each lever is pivotally supported within the housing by a pivotal connection between the lever and part of the housing.

37. An assembly as claimed in claim 36 in which the housing has a front wall, a rear wall and two opposing side walls and the or each lever is pivotally connected to the front and rear walls.
- 5 38. An assembly as claimed in claim 35 or in claim 37 in which each lever projects outwardly from the housing through a respective aperture formed in a one of the side walls.
39. An assembly as claimed in claim 38 in which the part of each lever which projects from the aperture forms a finger grip.
- 10 40. An assembly as claimed in any of claims 30 to 35 in which the or each lever is pivotally supported within the housing by a pivotal connection between the body and the respective lever.
41. A fluid dispensing device for spraying a fluid into a body cavity substantially as described herein with reference to the accompanying drawing.
- 15 42. A fluid discharge device substantially as described herein with reference to the accompanying drawing.
43. A housing assembly for a fluid discharge device substantially as described herein with reference to the accompanying drawing.

Abstract

A fluid dispensing device 5 is disclosed having a housing 9 and a pump action fluid discharge device 8. The pump action fluid discharge device 8 is arranged to be actuated by a pair of opposing levers 20, 21 which are pivotally connected to part of
5 the housing 9 and are driveably connect by a toothed drive 22a, 22b, 32a, 32b ; 23a, 23b, 33a, 33b to a container 30 forming part of the fluid discharge device 8.

When the levers 20, 21 are squeezed together the container 30 is urged towards a nozzle 11 of the fluid dispensing device 5 causing a pump forming part of the fluid discharge device 8 to dispense a single dose of fluid from the nozzle 11.

1/4

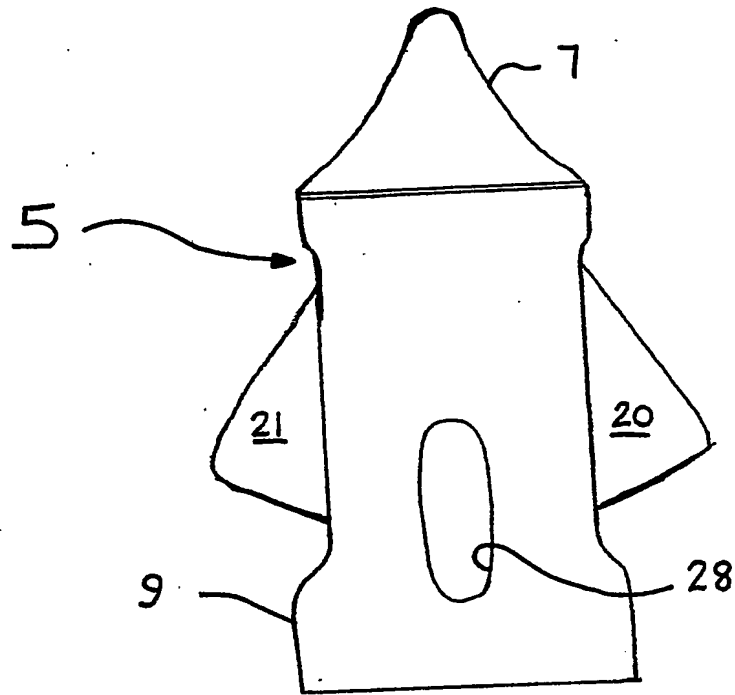


Fig.1

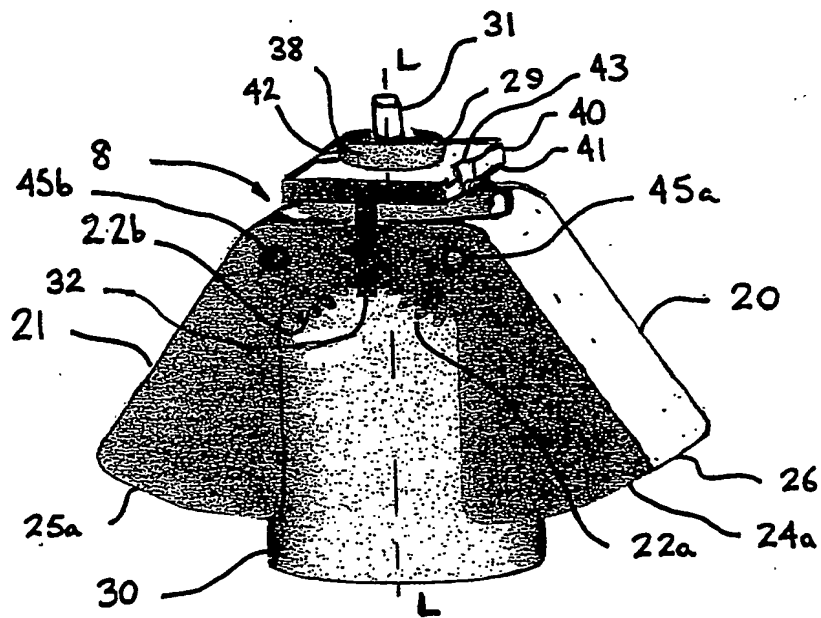


Fig.2

2/4

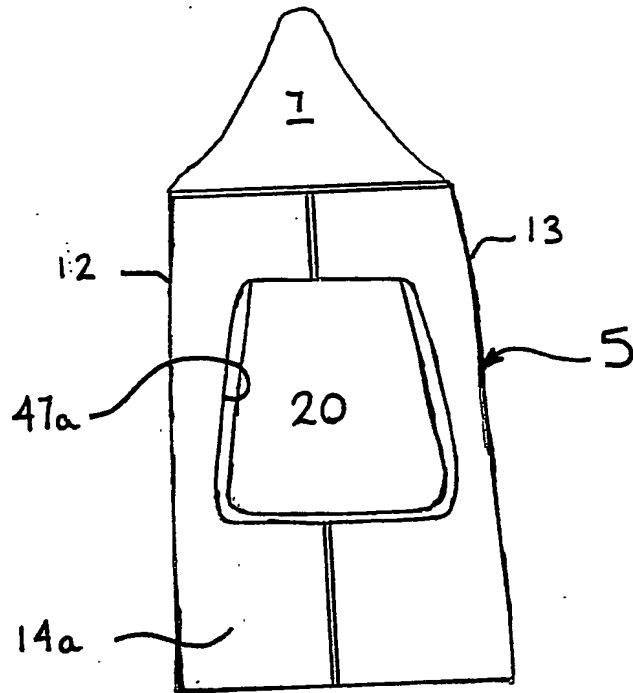


Fig.3

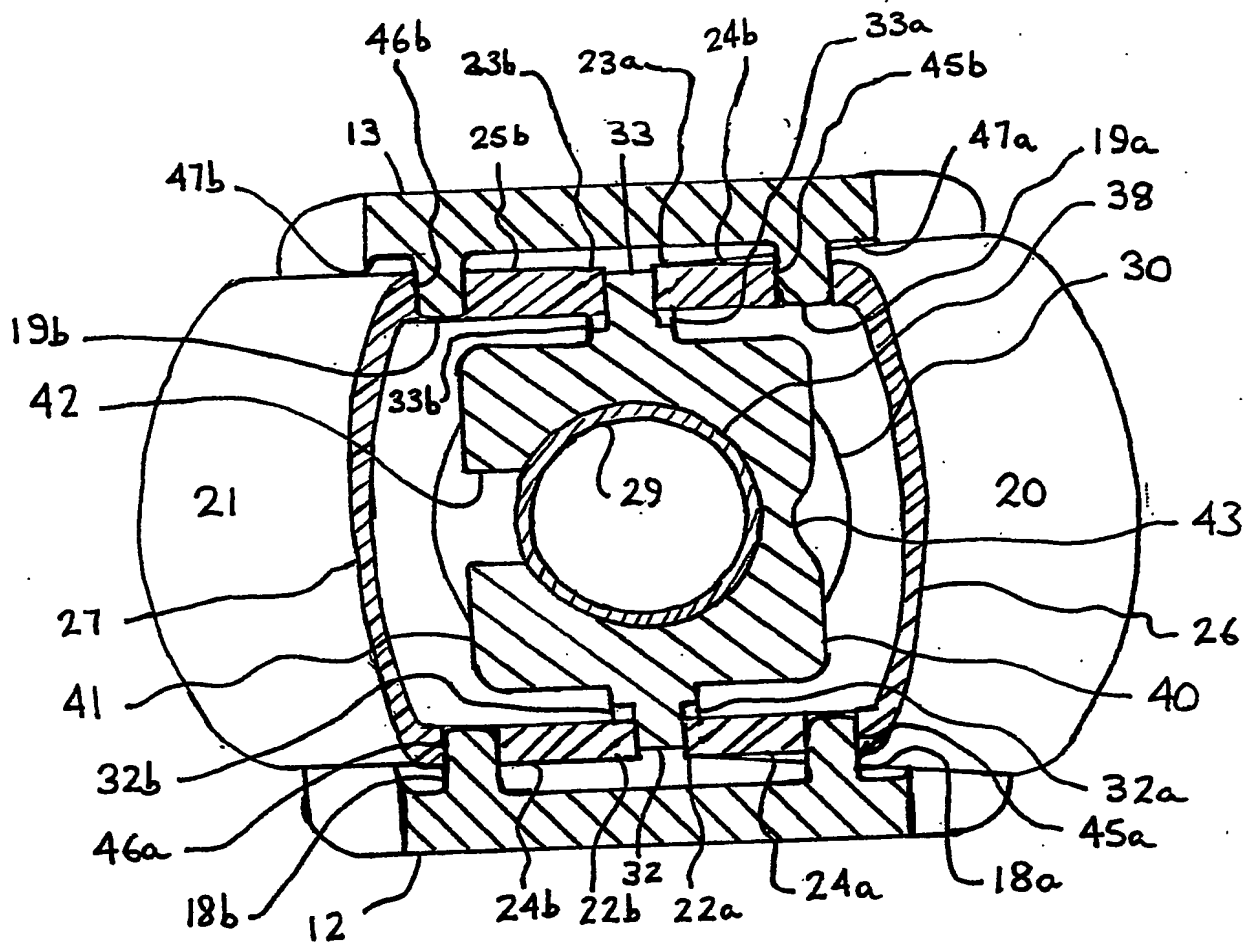


Fig. 6

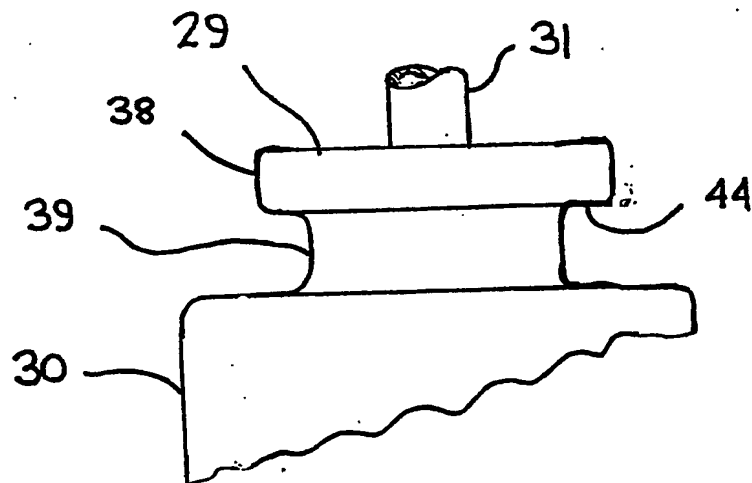


Fig. 7

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.